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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/602,272	02/16/1996	MICHAEL J. ELLIOTT	KIR96-01	4297

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	33

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/602,272	Elliott et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6, 8, 10, 12-32, and 34-50* is/are pending in the application.

4a) Of the above, claim(s) *16-28 and 38-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 8, 10, 12-15, 29-32, and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Response to Amendment

1. Claims 15 and 37 have been amended. Claims 16-28 and 38-50 remain withdrawn from consideration. Claims 6, 8-10, 12-15, 29-32 and 34-37 are under consideration.

Claim Rejections Maintained

2. The rejection of claims 6, 8, 10, 12-15, 29, 30, 32 and 34-37 under 35 U.S.C. 102(a) as being anticipated by Hommes et al (Gastroenterology, 1995, Vol. 108, No. 4, suppl., p. A838, as evidenced by Leardi et al (Italian Journal of Surgical Sciences, 1983, Vol. 13, pp. 197-201) and Le et al (US 5,919,492) is maintained for reasons of record.

3. The rejection of claims 6, 8, 9, 29, 30 and 31 under 35 U.S.C. 103(a) as being unpatentable over Hommes et al (Gastroenterology, 1995, Vol. 108, No. 4, suppl., p. A838, as evidenced by Leardi et al (Italian Journal of Surgical Sciences, 1983, Vol. 13, pp. 197-201) and Le et al (US 5,919,492) in view of Dhainaut et al (Critical Care Medicine, 1995, Vol. 23, pp. 1461-1469) is maintained for reasons of record. The embodiments of claims 6, 8, 29 and 30 are stated in paragraph 6, supra.

4. Applicant argues that Hommes et al does not teach every element of the claimed method. However, the claimed method is inherent in the treatment of Crohn's patients with anti-tumor necrosis factor antibody, cA2 as disclosed by Hommes et al. This is exemplified by Leardi et al who teach that Crohn's disease patients are at risk of developing thrombosis. Applicant further argues that Le et al does not remedy the deficiencies of Hommes and Leardi et al. This is not persuasive, as Le et al teach the specific embodiments of claims 10, 13, 32 and 35 which specify that the anti-TNF antibody binds to epitopes consisting of amino acids 87-108 and 59-80 of human tumor necrosis factor.

5. The rejection of claims 6 and 8 under 35 U.S.C. 102(b) as being anticipated by either of Arii et al (Circulation, 1994, Vol. 90, No. 4, part 2, p. I522, abstract No. 2811) or Vertrees et al (Asaio Journal, 1994, Vol. 40, pp. M554-M559) or Wakefield et al (Arteriosclerosis, Thrombosis and Vascular Biology, 1995, Vol. 15, pp. 258-268) is maintained for resaons of record.

6. Applicant argues that none of the cited references teaches each and every element of the claims as none of the references mentions thrombosis. This is not found persuasive. The claims are drawn to the prevention of thrombosis in a subject, therefore, the claimed method is inherent in every disclosure of the administration of the claimed antibody to a subject, as prevention necessarily embodies the administration of the claimed antibody before the onset of thrombosis.

7. The rejection of claims 6, 8, 9, 29, 30 and 31 under 35 U.S.C. 103(a) as being unpatentable over Hommes et al (Gastroenterology, 1995, Vol. 108, No. 4, suppl., p. A838, as evidenced by Leardi et al (Italian Journal of Surgical Sciences, 1983, Vol. 13, pp. 197-201) and Le et al (US 5,919,492) in view of Dhainaut et al (Critical Care Medicine, 1995, Vol. 23, pp. 1461-1469) is maintained for reasons of record. Applicant argues as the combination of Hommes et al and Leardi et al and Le et al is defected, the addition of Dhainaut et al does not serve to remedy the deficiency. This is not found persuasive for the reasons set forth in section X, above. Furthermore, claims 9 and 31 embody a humanized or resurfaced antibody or an antigen-binding fragment thereof that binds TNF and Dhainaut et al teaches said humanized antibody as CDP571 used clinically to treat septic chock, a disease mediated by high levels of circulating TNF.

8. The rejection of claims 6 and 8 under 35 U.S.C. 103(a) as being unpatentable over Fisher et al (Critical Care Medicine, 1993, Vol. 21, pp. 318-327) in view of Hopper et al (Blood, 1994, Vol. 84, pp. 483-489) or Jolin et al (Acta Anaesthesiologica Scandinavica, Supplementum, 1991, Vol. 95, pp. 40-52) is maintained for reasons of record.

9. The rejection od claims 6, 8, 10, 12-15, 29, 30, 32 and 34-37 under 35 U.S.C. 103(a) as being unpatentable over Le et al (US 5,656,272) in view of Hopper et al (Blood, 1994, Vol. 84, pp. 483-489) or Jolin et al (Acta Anaesthesiologica Scandinavica, Supplementum, 1991, Vol. 95, pp. 40-52) is maintained for reasons of record.

10. Applicant again argues that the cited references do not disclose all the embodiments of claims 6 and 8. This is not found persuasive. Le et al teach the treatment of Chron.' disease by the administration of an anti-TNF antibody, cA2, which binds to epitopes 87-108 and 59-80 of human TNF. Le et al teach that these antibodies have the ability to neutralize TNF pathological activity. Hooper et al teach that patients with AIDS are at risk for thrombosis due to high levels of TNF-alpha. Hooper et al further disclose that protein S deficiency which is caused by elevated levels of TNF alpha is associated with thrombosis. Jolin et al teach that patients with adult respiratory distress syndrome have elevated coagulation factors induces by TNF, thus it can be concluded that patients with adult respiratory distress syndrome are at risk of thrombosis. Jolin et al suggests that antibodies to TNF be used as therapeutic agents for patient exhibiting adult respiratory distress syndrome. Fischer et al teach the administration of an anti-TNF antibody to a patient suffering from elevated levels of TNF. Given these references it would be obvious to treat both AIDS patients who are at risk of thrombosis and adult respiratory distress syndrome patients, who have elevated levels of coagulation factors, and are therefore at risk of thrombosis with the anti-TNF antibody disclosed by Fisher et al as it is suggested by Jolin et al, that the administration of anti-TNF antibodies can be therapeutic to adult respiratory distress syndrome patients. Thus the references teach the antibodies which neutralize the activity of TNF and the administration of said antibodies to human patients. The pathologies of AIDS and adult respiratory distress syndrome which put patients affected thereby at risk for thrombosis due to elevated levels of TNF. In order to prevent or treat thrombosis in said patients it would be obvious to administer the disclosed neutralizing antibodies to TNF.

11. All other rejections and objections as stated in Paper No. 30 are withdrawn.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 22, 2002

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